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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/848,370	05/04/2001	Shawn R. Feaster	0207-0003P	6779

7590

03/20/2003

Office of the Staff Judge Advocate  
U.S. Army Medical Research and Materiel Command  
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Fort Detrick, MD 21702-5012

EXAMINER

SAUCIER, SANDRA E

ART UNIT PAPER NUMBER

1651

DATE MAILED: 03/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
**09/848,370**

Applicant(s)  
**Feaster et al.**

Examiner  
**Sandra Saucier**

Art Unit  
**1651**

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Dec 12, 2002
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-9 and 38-52 is/are pending in the application.
- 4a) Of the above, claim(s) 45-52 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9 and 38-44 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on May 4, 2001 is/are a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 4 6) ☐ Other: \_\_\_\_\_

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#### **DETAILED ACTION**

Claims 1-9, 38-52 are pending. Claims 1-9, 38-44 are considered on the merits. Claims 45-52 are withdrawn from consideration as being drawn to a non-elected invention.

#### ***Election/Restriction***

Claims 45-52 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention, the requirement having been traversed in Paper No. 6.

The traversal is on the grounds that the newly written claims all depend from claim 1 and should be grouped with the elected invention of Group I, claims 1-9. Please note that claims 38-44 have been included in Group I. However, claims 45-52 are considered to be distinct inventions because they have distinct end points and distinct steps leading to the distinct end points. Applicants have canceled the original claims 10-37 and have elected Group I, claims 1-9.

Upon the finding of an allowable independent claim, further method claims dependent upon the independent claim may be added upon request by applicant.

#### ***Information Disclosure Statement***

The listing of the references on PTO 1449 is incomplete. A proper citation includes AUTHOR, TITLE, JOURNAL, VOLUME, NUMBER, INCLUSIVE PAGES, (month), YEAR. The citations are missing the journal and title of the article.

AA1 has an incomplete journal name.

AC1 is missing the title.

AD1 is missing the title and has an incorrect journal name.

AE1 is missing the journal name.

AF1 has an incorrect journal name.

AG1 has an incomplete journal name.

AI1 has an incorrect journal name.

AJ1 has an incorrect journal name.

AK1 has an incorrect journal name.

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Also, no copy of AB1, AC1 or AD1 was found with the submitted form 1449.

MPEP37 CFR 1.98(b) requires that each U.S. patent listed in an information disclosure statement be identified by patentee, patent number, and issue date. Each foreign patent or published foreign patent application must be identified by the country or patent office which issued the patent or published the application, an appropriate document number, and the publication date indicated on the patent or published application. Each **publication** must be identified by **author** (if any), **title**, **relevant pages** of the publication, **date** and place of publication. The date of publication supplied must include **at least the month** and year of publication, except that the year of publication (without the month) will be accepted if the applicant points out in the information disclosure statement that the year of publication is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the particular month of publication is not in issue. The place of publication refers to the **name of the journal**, magazine, or other publication in which the information being submitted was published.

### *Specification*

The disclosure is objected to because of the following informalities: page 25, line 15, anemia is misspelled, page 28, line 11 should have a trademark designation, page 32, line 3 should have trademark designation, page 32, line 4 is missing information "available from was used.", page 43, line 12 is missing a trademark designation.

Appropriate correction is required.

### *Claim Rejections - 35 USC § 112*

#### INDEFINITE

Claims 1-9, 38-44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites "with a sensitivity coefficient of each of substrate for the protein". Should this be "using a sensitivity coefficient for each substrate and for each protein"?

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Further, claim 1 is missing steps since it recites "with a sensitivity coefficient", but does not incorporate a method to determine this coefficient. It does not appear that "sensitivity coefficient" is a known term of art; thus, to make the claim distinct and clear, the method for determining this coefficient should be incorporated into the claim. It also does not incorporate a method of using this "sensitivity coefficient". The coefficient appears to be plucked from the air and then not employed in any discernable manner.

Claim 1 is also missing a reaction from which the activity can be monitored. An activity of a test sample cannot be determined solely by using a coefficient. A coefficient is a constant, not an activity measurement.

Further, should more than one substrate be employed in claim 1? Please carefully clarify the claim.

Claim 2 recites "each substrate" but no "substrates" are seen in the independent claim.

Claim 3 does not tell how to "extract" each sensitivity coefficient and is, thus, incomplete and unclear. Mathematical relationships are better expressed in mathematical terms, not chemical ones.

The steps of claim 4 are unclear and the method cannot be understood in these terms.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action: A person shall be entitled to a patent unless (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent, (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 5, 38, 39 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by US 5,674,688 [A].

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The claims are directed to a method of determining the activity of a protein wherein the protein belongs to a plurality of proteins that have similar or overlapping properties toward a plurality of substrates comprising:

determining the activity of the protein with a sensitivity coefficient of each substrate for the protein.

The references are relied upon as explained below.

US 5,674,688 discloses a method of assaying structurally related analytes comprising reacting the analytes with a panel of reactive reagents which differ in reactivity with the related analytes and creating a "profile" of reactivity. In the absence of clarity in the claim regarding "sensitivity coefficient", the reactivity profile is considered to be its equivalent.

Claims 1-9, 38, 39, 41-43 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Chemnitius *et al.* [U].

Chemnitius *et al.* disclose a differential inhibition method for the quantitative determination of cholinesterase isoenzymes. Various differential values of inhibition are determined for each isozyme. Figure 1 shows the various isozymes incubated with different concentration of inhibitor. Table 1 shows the results obtained from a differential inhibition assay on heart muscle where the activities of the individual isozymes in the mixed sample are calculated. This appears to be the same result as the instant result. Whether one calls certain constants calculated "sensitivity coefficients" or some other name such as a rate constant or other term, is of no consequence. The method step of "extracting" each sensitivity coefficient without inclusion of the mathematical identity of the "sensitivity" coefficient, is sufficiently broad to include the manipulations as described in Chemnitius *et al.*

### ***Claim Rejections – 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action: (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 40-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,674,688 [A].

The claims are directed to the use of various biological fluids and tissues as the source of the sample. Claim 42 recites the use of a chromogenic substrate in the reaction so that the reaction may be monitored by a spectrometer.

The references are relied upon as explained below.

US 5,674,688 discloses that the sample may be biological fluids or tissues, without limiting the types of fluids or tissues (col. 3, l. 16); and teaches that any type of reaction may be measured (col. 4, l. 2). Since chromatogenic substrates are well known in the art of enzymatic activity monitoring, one of ordinary skill in the art may select a chromatogenic substrate which is useful for the specific enzyme activities wished to be monitored. Further, this method is said to be useful to monitor drugs and therapeutic materials which either enhance or inhibit activity or concentration of the target family of proteins.

One of ordinary skill in the art would have been motivated at the time of invention to make these substitutions in order to obtain the results as suggested by the references with a reasonable expectation of success. The claimed subject matter fails to patentably distinguish over the state of the art as represented by the cited references. Therefore, the claims are properly rejected under 35 U.S.C. § 103.

Cited as being of interest are Simeon-Rudolf *et al.* and Durrani *et al.*

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1651. The supervisor for 1651 is M. Wityshyn, (703) 308-4743. The normal

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work schedule for Examiner Saucier is 8:30 AM to 5:00 PM Monday and Tuesday and 8:30 AM to noon on Wednesday.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Saucier whose telephone number is (703) 308-1084. Status inquiries must be directed to the Customer Service Desk at (703) 308-0197 or (703)-308-0198. The number of the Fax Center for the faxing of official papers is (703) 872-9306 or for after finals (703) 872-9307.

A handwritten signature in black ink, appearing to read 'Sandra Saucier', with a stylized flourish at the end.

Sandra Saucier  
Primary Examiner  
Art Unit 1651  
March 19, 2003